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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORD, JOHN M	
ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/762893	Schindler et al
Examiner	**Group Art Unit**
T. M. Ford	1624

—The MAILING DATE of this communication appears on th cover sheet beneath th correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on Dec 23, 2002.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1--5, 11--15 and 22-23 is/are pending in the application.

Of the above claim(s) 11-12, 14, 19, 22 and 23 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1--5, 13-15 and 20 & 21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or lecti n requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Int rview Summary, PTO-413

☐ N tice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Acti n Summary

Applicants' response of Dec. 23, 2002, is noted.

The claims in the application are claims 1--8, 11--15 and 18--23.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph. Heteroaryl is defined on page 4 of the most recent response. One or more is open. Applicants have been careful in their claim drafting to indicate a reasonable number of hetero atoms in the ring. However, heteroaryl provides for the open ended "one or more" heteroatoms, 4, 5, 6? Even 1 to 3 is a huge number of rings that the reader has to draw out and classify, oxazines, oxadiazines, thiazines, thiadiazines, dithiazines, before the pyrimidine of formula I. This is too much burden on the reader. Not a fair burden in return for applicants receiving a 17/20 monopoly on compounds they have not demonstrated they even made.

Which brings us to a 35 U.S.C. 112, 1st paragraph rejection of this heteroaryl expression. The specification does not provide adequate exemplification for the breadth of the expression, because of the use of "or more" in regard to the hetero atoms in the unknown, but claimed ring.

Claims 2--8 and 12--15 and 20--21 are rejected as being dependent on a rejected claim.

Applicants have been asked to elect one reasonable, demonstratable use and they have not done so. The claims demonstrate more than one use of the compounds. MPEP 806.05(h) provides for restricting these method claims out altogether where it can be shown that the compounds as claimed may be used for more than one purpose. The claims become evidence claims to that allegation.

Accordingly, claims 11, 12, 18, 19, 22 and 23 stand non-elected and withdrawn.

A cardiovascular disorder is obviously not one. A cardiovascular disorder, in claim 22, associated with low cGMP levels is a laboratory test, and does not set forth a real world disease.

Claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs.

What is intended by heteroaryl?

Heteroaryl is a huge area of Chemistry, that completely overshadows the formula I.

The heteroaryl term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

Judge Smith noted many different definitions for aryl in the footnotes of In re Sus, 134 USPQ 301. Heteroaryl, likewise, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider those heterocyclic, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The heteroaryl term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.

Conception of what the intended heteroaryl ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic groups for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of scope 112; second is that language is so broad that it causes claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from first paragraph of section 112. Merits of the language in claim must be tested in light of these two requirements.

The heteroaryl variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heteroaryl concept is so broad that cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here is the specification. Conception should not be the role reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second

paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heteroaryl rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1, 3, 4, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of hetero aryl applied by applicant, has no idea where the hetero atoms are in this unknown ring.

How many hetero atoms are there in the unknown, but claimed ring?

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heteroaryl term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quire large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is a pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicants breadth of heteroaryl produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heteroaryl expression in claim 1 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, United Carbon Co. Vs. Binney & Smith Co., 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockhead Aircraft Corp. Vs. United States, 193 U.S.P.Q. 449, "claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

The heteroaryl expression includes adjacent O/S combinations that are unstable. That open ended breadth cannot be allowed. The claim cannot be completely searched, here, until we know what applicants intend by heteroaryl, see In re Wiggins; 179 USPQ 421. Where is the support in the specification?

Similarly, the USPTO only recognizes: C,N,O,S,Se or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heteroaryl.

Heterocyclic is not just a substituent; it is a whole body of art, larger than the claimed here. Researchers often spend their entire life on hetero N heterocyclic compounds, without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

Accordingly, claim 1 is rejected under 35 U.S.C. 112, 1st and 2nd paragraphs. What is being claimed? Where is the adequate representative exemplification in the specification?

In an area of high interferences, you have to think what happens after the application is allowed. Counts are impossible to construct where there is no specific support in the specification for the term as species; In re Ruachig, 154 USPQ 118.

A count cannot be constructed for heteroaryl, as it has no adequate species support; Freerksen vs. Gass, 21 USPQ (2nd) 2007.

Applicants should not be permitted to pre-empt future work of others. Someone may find a way to reduce the strain between adjacent hetero atoms in a ring by changing the bond angles to make the compound, only to find applicants already claimed it here, but never made it.

MPEP 806.05(h) provides for restriction of the method of use claims, where they show more than one use of the compounds. Applicants may (if they wish) elect one clear, demonstrable method of use.

Claims 11, 12, 18, 19, 22 and 23 are noted. The use statements therein are considered non-specific, or more than one.

The Utility needs to relate to the real World of Commerce.

The Utility in claims 9, 11, 12, 18, 19, 22 and 23 are too broadly stated.

Applicants need to elect one method of use (See 37 CFR 1.475) and make the statement specific.

The utility statement in claim 22 cannot be acceptable as one specific utility. The recent utility guidelines set by USPTO require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 689, which requires that utility be developed to a point where "specific

benefits exist is currently available form" similar is the "immediate benefit to the public: standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is whether the invention has been brought to such perfection as to be capable of practical employment. This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

37 CFR 1.475 and PCT Rule 13.2, provides for one method of use to be examined with the elected compounds. A broad disclosures of Utility as in the cited claims 11, 12, 18, 19, 22 and 23 cannot be deemed in compliance with the above discussion.

The U.S.P.T.O. has amended the guidelines to clarify "specific utility." The court focused on the fact that the applicant failed to identify a "Specific utility" in Brenner v. Manson.

This requirement of one specific utility is consistent with 37 CFR 1.475; the Unity of Invention Practice in International Applications and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2.

Therefore, applicants should limit the method claims to a sole "specific utility".

Applicants need to pick one believable utility for the claims.

The "how to use" requirements of 35 U.S.C. 112 are not met by disclosing only a pharmacological activity of the claimed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Driedrich (CCPA 1963) 318 F.2d 946, 138 USPQ 1`28; In re Gardner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138. Thus, where the claimed compounds are not structurally similar to known compounds having the same activity and their pharmaceutical properties could not be predicted their chemical structure,

a disclosure that they possess a particular activity against a pathological organism (antitubercular activity) may not suffice as a description of how to use as required by 35 U.S.C. 112. In re Moureu et al. (CCPA 1965) 345 F2d 595, 145 USPQ 452.

Statements of utility which relate to or imply the treatment of a disease are subject to closer scrutiny. Ex parte Moore et al. (POBA 1960) 128 USPQ 8.

Where utility is based on the alleged enhancement of activity of known medicinals. The CCPA up held the Examiner's requirement that the applicant submit evidence which substantiated the allegation, unless one skilled in the art would accept them as obviously valid and correct. In re Novak et al., (CCPA 1962) 306 F2d 924, 134 USPQ 335.

Consider one utility from claim 23, that they can demonstrate.

JOHN M. FORD
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GROUP - ART UNIT 1624

John M. Ford:jmr

February 3, 2003